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EXAMINER

CROUCH, DEBORAH

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/05/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/225,233

Applicant(s)

CAMPBELL ET AL.

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 92-130 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 92-130 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/802,282.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Applicant's arguments filed February 10, 2003 in paper no. 26 have been fully considered but they are not persuasive. The amendment has been entered. Pending claims are 92-130. The declaration by David Wells has been considered but not deemed persuasive.

Applicant is advised that should claims 101-107 be found allowable, claims 108-115 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 92-127 and 130 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 57-68 and 71 of copending Application No. 09/658,862. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The claims are to a product, nonhuman embryo clones and nonhuman mammalian clones, produce by process. While the process steps themselves are obvious over each other, the products are identical.

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Applicant argues that the inventions presently claimed and those in '862 are not the "same" invention as defined under 101 because the present claims could be infringed without infringing those in '862. This argument is not persuasive.

The products, while made by materially different and separate methods, are the same. There is no patentable distinction between them. The methods of making do not affect the product being claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 92-127 and 130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,252,133 B1. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because

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the presently claimed cloned nonhuman embryos, cloned nonhuman mammals and reconstituted nonhuman mammalian oocyte are made a process claimed in '133.

The present claims are drawn to reconstituted nonhuman mammalian embryo clones, nonhuman mammal clones and reconstituted nonhuman mammalian oocyte that contain the same set of chromosomes as a pre-existing, nonhuman, non-embryonic mammal. The reconstituted mammalian oocyte and reconstituted embryo clone is produced by nuclear transfer of a quiescent diploid donor cell or in the G0 phase of the cell cycle into an suitable recipient cell of the same species as the cell, followed activation and incubation to produce an embryo. To produce the mammal, the embryo clone is transferred to a recipient female of the same species as the cell. The donor cell is from a pre-existing, nonhuman, non-embryonic mammal. Claim 1 of '133 are to methods of reconstructing an embryo of a nonhuman mammal comprising a donor diploid cell in the G0, quiescent, phase of the cell cycle into an unactivated, enucleated MII phase oocyte of the same species as the cell, maintaining the reconstructed embryo or oocyte without activation, activating the reconstructed embryo, and, transfer the reconstructed embryo to a female of the same species, to produce the mammal. The donor cells of the present claims fall within the scope of "diploid donor cell" of the claims in '133, and donor cells are defined in the specification as coming from a pre-existing, nonhuman mammal non-embryonic mammal. '133 claims a mammal is produced by transferring the embryo to a female mammal of the same species.

Therefore, at the time of the instant invention, it would have been obvious to the ordinary artisan to produce a cloned nonhuman embryo, a cloned nonhuman mammal or reconstituted nonhuman mammalian oocyte as presently claimed given the method steps of claim 1 in '133.

Claims 92-127 and 130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13-21 of

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U.S. Patent No. 6,147,276. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed cloned nonhuman embryos, cloned nonhuman mammals and reconstituted nonhuman mammalian oocyte are made a process claimed in '276.

The present claims are drawn to reconstituted nonhuman mammalian embryo clones, nonhuman mammal clones and reconstituted nonhuman mammalian oocyte that contain the same set of chromosomes as a pre-existing, nonhuman, non-embryonic mammal. The reconstituted mammalian oocyte and reconstituted embryo clone is produced by nuclear transfer of a quiescent diploid donor cell or in the G0 phase of the cell cycle into an suitable recipient cell of the same species as the cell, followed activation and incubation to produce an embryo. To produce the mammal, the embryo clone is transferred to a recipient female of the same species as the cell. The donor cell is from a pre-existing, nonhuman, non-embryonic mammal. Claims 1-10 and 13-21 of '276 are to methods of reconstructing a nonhuman mammalian embryo comprising transferring the nucleus of a quiescent donor diploid cell, G0 phase of the cell cycle, into a suitable enucleated recipient cell of the same species, defined in the '276 specification as being an MII enucleated oocyte, activating the reconstructed embryo, incubating the reconstituted cell so that an embryo develops and, transfer the reconstructed embryo to a female of the same species, to produce the mammal. The donor cells are defined in the specification as coming from a pre-

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existing, nonhuman mammal non-embryonic mammal. The remainder of the present method steps are contained in the method steps in '276.

Therefore, at the time of the instant invention, it would have been obvious to the ordinary artisan to produce a cloned nonhuman embryo, a cloned nonhuman mammal or and reconstituted nonhuman mammalian oocyte as presently claimed given the method steps of claims 1-10 and 13-21 in '276.

Applicant agreed to file a terminal disclaimer to U.S. Patent No. 6,252,133 B1 and U.S. Patent No. 6,147,276 once allowable subject matter is identified.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 92-125, 128 and 129 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 92, 101, 108, 116, 121, 128 and 129 each contain the phrase "same set of chromosomes." However, the specification does not provide support for this phrase. Applicant should specifically point out where in the specification support for this phrase can be found. There is no discussion in the specification that the clones contain a "same set of chromosomes. Further, this phrase does not occur in the originally filed claims. Without support, there is no evidence that applicant contemplated that the clones would contain "same set of chromosomes" at the time of filing.

In addition, claim 128 is drawn to nonhuman, non-embryonic mammal from which a differentiated cell has been taken and a clone thereof, wherein the clone has the same set

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of chromosomes as the nonhuman mammal. Claim 129 is drawn to a cell culture comprising nonhuman mammalian differentiated cells and a clone thereof, wherein the cloned has the same set of chromosomes as the cells in the culture. The specification does not contemplate either a nonhuman, mammal and a clone of the mammal nor nonhuman mammalian differentiated cells and clone produced from the cells as a product, kit or any other invention. Applicant needs to provide specific support for the contemplation of the two products as one invention.

Claims 116 and 121 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods where the donor nucleus is inserted into an enucleated cell, does not reasonably provide enablement for insertion into non-enucleated cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At the time of filing, the art recognized that the recipient oocyte in nuclear transfer proceedings needed to be enucleated so that the resulting reconstructed embryo would be diploid.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 92, 95, 101, 108, 109, 116, 119, 121, 123, and 126-130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 92, 101, 108, 116, 121 and 126-130 has the phrase "has the same set of chromosomes as a pre-existing mammal." However, there is no definition of "same set" in the specification. Does applicant mean the same chromosomes that were in the parent,



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chromosomes that have identical nucleotide sequence, chromosomes that have the the same karyotype or a group of chromosomes having the same number as the pre-existing mammal? Applicant is requested to point out the definition for this phrase by page and line number.

Claims 92(c) and 126 states "embryo clone develops" which is confusing as to what the clone becomes by virtue of developing.

Claims 92(c), 116, 121, 126 and 130 states "is capable of developing to term" which is confusing as to the metes and bounds of the claim. Is an embryo that doesn't develop to term included in the claim? If only embryos that develop to term are included, won't the embryo be gone by the time the subject matter is realized? If the embryo isn't permitted development to term, is it included in the subject matter of the claim?

Claims 95, 109, 119 and 123 are confusing as to further limiting claim 92. Claim 92 states "a cell obtained by culture," which clearly would be a cultured cell. How could a cell be obtained from culture if it isn't cultured?

Claims 126 and 127 are unclear as if the donor cell is genetically modified, then the resulting mammalian embryo or mammal cannot be a clone.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 92-95,101,102,108,110,116-125 and 130(sheep) remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by McLaughlin et al (1990) Reproduction Fertil. Develop. 2, 619-622 for reasons presented in the office action mailed October 9, 2002 in paper no. 23.

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McLaughlin teaches the production of reconstituted sheep embryos and sheep (Merino lambs) by nuclear transfer of the reconstituted sheep embryos, where the donor nucleus is from sheep embryonic cells (page 620, parag. 2-5, and page 621, parag. 1). Both the sheep embryo and sheep of McLaughlin contains the same set of chromosomes as an individual sheep, that is the same chromosomes as the donor sheep. The source of the donor nucleus, be it sheep embryonic cells as in McLaughlin or a quiescent sheep diploid donor cell as claimed, does not provide a patentable distinction on the resulting sheep embryo or sheep. The source of the donor nucleus does not alter the resultant sheep embryo or sheep such that the sheep embryo or sheep encompassed by applicant's claims are patentably distinct from those of McLaughlin et al.

Claims 92-94,96,101,103,108, 109,111,116-125 and 130 (pig) remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Prather et al (1989) Biology of Reproduction 41, 414-418 for reasons presented in the office action mailed October 9, 2002 in paper no. 23.

Prather teaches the production of reconstituted pig embryos and pigs by nuclear transfer of the reconstituted pig embryos, where the donor nucleus is from a pig embryonic cell (page 415, col.1, parag. 1 to page 416, line 8, and page 416, col. 2, lines 8-10). Both the pig embryos and pig of Prather contains the same set of chromosomes as an individual pig, that is the same chromosomes as the donor pig. The source of the donor nucleus, be it pig embryonic cells as in Prather or a quiescent pig diploid donor cell as claimed, does not provide a patentable distinction on the resulting pig embryo or pig. The source of the donor nucleus does not alter the resultant pig embryo or pig such that the pig embryo or pig encompassed by applicant's claims are patentably distinct from those of Prather et al.

Claims 92-94,97,101,104,108,109,112,116-125 and 130 (goat) remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yong et al (1991) Threigenology 35, page 299 for reasons presented in the office action mailed October 9, 2002 in paper no. 23.

Yong teaches the production of reconstituted goat embryos and goats by nuclear transfer of the reconstituted goat embryos, where the donor nucleus is from a goat embryonic cell (parag. 2, and Table). Both the goat embryo and goats of Yong contains the same set of chromosomes as an individual goat, that is the same chromosomes as the donor goat. The source of the donor nucleus, be it goat embryonic cells as in Yong or a quiescent goat diploid donor cell as claimed, does not provide a patentable distinction on the resulting goat embryo or goats. The source of the donor nucleus does not alter the resultant goat embryo or goats such that the goat embryo or goats encompassed by applicant's claims are patentably distinct from those of Yong et al.

Claims 92-94,98,101,105,108,109,113,116-125 and 130 (mouse) remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cheong et al (1993) Biology of Reproduct. 48, 958-963 for reasons presented in the office action mailed October 9, 2002 in paper no. 23.

Cheong teaches the production of reconstituted mouse embryos and mice by nuclear transfer of the reconstituted mouse embryos, where the donor nucleus is from a mouse embryonic cell (page 959, col. 1, parag. 2 to col. 2, line 10 and page 962, Table 4). Both the mouse embryo and mice of Cheong contains the same set of chromosomes as an individual mouse, that is the same chromosomes as the donor mouse. The source of the donor nucleus, be it mouse embryonic cells as in Cheong or a quiescent mouse diploid donor cell as claimed, does not provide a patentable distinction on the resulting mouse embryo or mice. The source of the donor nucleus does not alter the resultant mouse embryo or mice

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such that the mouse embryo or mice encompassed by applicant's claims are patentably distinct from those of Cheong et al.

Claims 92-94,99,101,106,108,109,114,116-125 and 130 (rabbit) remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yang et al (1992) Biology of Reproduct. 47, 636-643 for reasons presented in the office action mailed October 9, 2002 in paper no. 23.

Yang teaches the production of reconstituted rabbit embryos and rabbits by nuclear transfer of the reconstituted rabbit embryos, where the donor nucleus is from a rabbit embryonic cells (page 636, col. 2, parag. 2 to page 639, through parag. 2; page 640, col. 2, parags. 1 and 2, and page 642, Table 4). Both the rabbit embryo and rabbit of Yang contains the same set of chromosomes as an individual rabbit, that is the same chromosomes as the donor rabbit. The source of the donor nucleus, be it rabbit embryonic cells as in Yang or a quiescent rabbit diploid donor cell as claimed, does not provide a patentable distinction on the resulting rabbit embryo or rabbit. The source of the donor nucleus does not alter the resultant rabbit embryo or rabbit such that the rabbit embryo or rabbit encompassed by applicant's claims are patentably distinct from those of Yang et al.

Claims 92-94,100,101,107,108,109,113,116-125 and 130 (cows) remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sims et al. (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147 October 9, 2002 in paper no. 23.

Sims teaches the production of reconstituted bovine embryos and bovines by nuclear transfer of the reconstituted bovine embryos, where the donor nucleus is from a bovine cultured inner cell mass cell (page 6145, col. 2, parag. 2, lines 1-7 and page 6146, col. 1, parag. 2, lines 6-11). Both the bovine embryo and bovine of Sims contains the same set of chromosomes as an individual bovine, that is the same chromosomes as the donor bovine. The source of the donor nucleus, be it bovine inner cell mass cell as in Sims or a quiescent

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bovine diploid donor cell as claimed, does not provide a patentable distinction on the resulting bovine embryo or bovine. The source of the donor nucleus does not alter the resultant bovine embryo or bovine such that the bovine embryo or bovine encompassed by applicant's claims are patentably distinct from those of Sims et al.

Claims 126 and 127 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 95/17500 published 29 June 1995 (Stice) October 9, 2002 in paper no. 23.

Stice teaches transgenic nonhuman mammalian embryos and transgenic nonhuman mammals produced by nuclear transfer where the nuclear donor is an embryonic cell comprising a genetic modification (page 33, lines 14-24). The source of the donor nucleus, be it a genetically modified nonhuman embryonic cell as Stice teaches or a genetically modified non-embryonic, nonhuman mammalian cell as claimed, does not provide a patentable distinction on the resulting genetically modified nonhuman embryo or genetically modified nonhuman mammal. The source of the donor nucleus does not alter the embryo or mammal such that the embryo or mammal encompassed by applicant's claims is patentable distinct from those of Stice et al. Thus, Stice clearly anticipates the claimed invention.

Applicant argues that each cited reference begins by the conventional process of producing embryos by fertilization of an egg by a sperm. Applicant argues that conventional reproduction and cloning using a conventional embryo as the source of donor cells do not permit the selection of an existing mammal that has advantageous characteristics and make a genetic copy of it. Applicant argues that the use of a differentiated cell from the mammal to be cloned prevents any unpredictability resulting from the mixing of parental genomes. Applicant argues that there is need for only one parent to produce the claimed mammals, and not two as in the references. Declarant Wells supports applicant's arguments in stating

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that the references do not teach the production of mammals from "one parent" or mammals that contain the same set of chromosomes as a prior existing embryo or mammal.

Regardless of how the mammals were actually produced in the prior art, there are no identifying characteristics or features of the claimed mammals that would distinguish them from the mammals in the art. For example, the Merino sheep taught by McLaughlin cannot be distinguished from Merino sheep of applicant's claims. In a side-by-side comparison of McLaughlin's sheep and sheep of applicant's claims, there would be no patentably distinguishing differences. Another way to look at the issue, is if there were two Merino sheep in the yard, how could one tell which was produced by sexual reproduction and which was produced by cloning; which had a genome from two parents, versus one that had one a genome of one parent. Once the embryo or mammal is made, how it was made cannot be discerned. In fact, one of the sheep would be prior existing. Again, the examiner does not see any patentably distinguishing characteristics or features of the sheep presently claimed and those of McLaughlin. This same argument applies to the claims to pig, goat, mouse, rabbit and cow as claimed. The limitation provided by "same set of chromosomes as the pre-existing mammal" does not distinguish from the art. In fact it admits that the mammals of the claims are the same as the nuclear donor mammals, and thus known in the art at the time of filing. Thus, a clone of any one of the mammals in the cited prior art would be the same as a mammal of the claims. They both would have the "same set of chromosomes."

With regard to "same set of chromosomes," without a clear definition of what is meant by this phrase, and mammal of the same species would have the same number of chromosomes, the same genes on the chromosomes and the same chromosome structure, such as by RFLP analysis, as examples. In this regard, if same set means same number of chromosomes, then the mammals in the cited prior art would certainly anticipate the claims. Further, if same set means same karyotype, same RFLP analysis or same genomic

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sequence, applicant needs to supply such information as the patent office does not have facilities to test the art products and the claimed products. See *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977).

Applicant argues that patentability should turn on novelty and nonobviousness, and not how the mammal looks and behaves. Applicant argues that the limitation that the cloned embryo and mammal has the same set of chromosomes of a pre-existing, non-embryonic mammal from which a differentiated cell has been taken is the distinguishing feature. Applicant questions the statutory authority for a side-by-side comparison of products. Applicant states that very few patentable articles are immediately recognizable as being patented unless they are marked.

The lack of novelty is the basis for the art rejections of record. The claimed cloned embryos and mammals are not novel because they are copies of embryos and mammals that existed before. References to looks and behavior in the previous office action were meant to establish that there are no features of the claimed embryos and mammals due to the genome content. These cloned embryos and mammals are indistinguishable, and that they neither look nor behave any differently than those in the cited art. The source of genome or the number of parents do not affect the resultant mammals such that patentable differences arise. The fact is no difference could be told between a three year old "nuclear donor" mammal and its clone as an example. This is the basis of the rejection. The clone and the nuclear donor mammal are indistinguishable, or if they aren't applicant has not argued or stated such distinction. A side-by-side comparison doesn't require statutory authority. It is merely one method through which the prior art mammals and those of the claims can be distinguished. Further, the side by side comparison was not intended to be only for physical differences. A side by side comparison provides no differences between the mammals of the cited art and those of the claims in any area of comparison. The genomes

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are the same, and, thus, the mammals are duplicates of one another. How can the mammal in the art differ from that of the claim when they are genetically identical? To be complete, none of the examiner's arguments were directed to the need to mark a product for infringement purposes. That is beyond the scope of an examiner's function, as stated by applicant.

Applicant states that they do not contest that a cloned cow or a cloned cow embryo covered by the present claims will generally look like any other cow or cow embryo clone, including those taught in the references and the parent animals from which the clone derives. Applicant argues that the examiner is ignoring their limitations and that these limitations are absent in the cited art. Applicant argues that the mammals and mammalian embryos cited are not clones of a pre-existing, non-embryonic mammal from which differentiated cells have been taken. Applicant argues that this is a structural limitation that distinguishes the claimed embryos and mammals from those in the cited prior art.

The limitation "has the same set of chromosomes as a prior existing mammal" is not a structural limitation to the cloned embryo or product. This does not provide any type of feature that can distinguish the prior mammal from the cloned product. A clone of the mammals of the art, or their embryos, cannot be distinguished structurally from the donor prior-existing mammal. The donor and their clones would be identical genomically.

Applicant argues that it is not possible for a clone and the nuclear donor not to be distinguished. Applicant argues that the phenotype of any mammal is determined by genetic and environmental factors. Applicant argues that since the mammals of the claims would have different genomic compositions and be raised in different environments, the mammals and the clones will have distinguishing characteristics. Applicant argues that the differences in chromosomal content could be easily determined. Applicant argues that the clones and



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the parent animal would be of different ages. This argument is supported by the Dr. Wells, declarant.

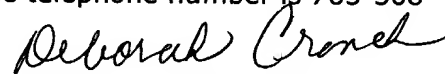
The claims do not contain any limitations to phenotypic characteristics of the cloned mammals over those of the art. Any such features applicant should include in the claim so that these features can be examined. While genetic differences can be distinguished by known methods, the methods supplied by Dr. Wells would not find differences between the mammals and embryos of the cited prior art and their clones.

Furhtermore, the claims state "pre-existing mammal." This includes mammal embryos. As the cited prior art produced clones from prior existing mammal embryos, the cited art clearly anticipates the "pre-existing mammal."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Reynolds, SPE of AU 1632 whose telephone number 703-305-4051. The examiner can normally be reached on M-Th.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

  
Deborah Crouch, Ph.D.  
Primary Examiner  
Art Unit 1632

D.C.  
May 2, 2003